AUG 5 - 2005

K051883

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5™ EEG Module, E-EEG and Datex-Ohmeda S/5™ EEG Headbox, N-EEG and Accessories

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

July 9, 2005

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5™ EEG Module, E-EEG and Datex-Ohmeda S/5™ EEG Headbox, N-EEG and Accessories.

COMMON NAME:

EEG Measurement Module, Headbox, and Accessories

CLASSIFICATION NAME:

The following Class II classification appears applicable:

Product Code	Classification Name	CFR Section
GWQ	Electroencephalograph	882.1400
GWJ	Stimulator,Auditory,Evoked response	882.1900
IKN	Electromyograph, diagnostic	890.1375

The following Class I classification appears applicable:

GWS	Electroencephalogram (EEG) signal spectrum analyzer	882.1420

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NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5™ EEG Module, E-EEG and Datex-Ohmeda S/5™ EEG Headbox, N-EEG and accessories is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M- EEG Module (K000892).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Datex-Ohmeda S/5™ EEG module, E-EEG is a single-width plug-in parameter module for a a Datex-Ohmeda modular monitoring system. The Datex-Ohmeda EEG module, E-EEG is for controlling the EEG, FEMG and AEP measurements in the N-EEG. The Datex-Ohmeda EEG headbox, N-EEG is a separate preamplifier and measurement unit for EEG, FEMG and AEP measurements. N-EEG can measure up to 4 real-time EEG waveform channels and an FEMG measurement from one channel. It can also measure AEP from two channels. The N-EEG can only be used with the Datex-Ohmeda EEG module, E-EEG.

The Datex-Ohmeda EEG module, E-EEG can be used with the following Datex-Ohmeda modular monitors:

S/5™ Anesthesia Monitor (AM) with main software S-ANE99(A) or L-ARK99(A) or newer

S/5™ Compact Anesthesia Monitor (CAM) with main software S-ANE99(A) or L-ARK99(A) or newer

S/5™ Critical Care Monitor (CCM) with main software L-ICU99(A) or newer.

S/5™ Compact Critical Care Monitor (CCCM) with main software L-ICU99(A) or newer.

The raw EEG signal is displayed from all the monitored channels. The waveform size, color and sweep speed can be adjusted. Spectral analysis is performed on all of the measured EEG channels. Total power is calculated, and several parameters are calculated based on the power spectrum of the signal. The burst suppression pattern is detected, and suppression ratio is calculated. All the calculated parameters can be selected on the display, and trended. For auditory evoked potentials, the stimulation intensity and frequency can be set, and the number of averaged responses can be determined. The averaged AEP can be stored and markers can be set manually. Six sets of AEP's can be stored and printed. One of the saved responses can be selected as a reference on screen. Electrode impedance is measured automatically, when the electrodes are attached, and during monitoring at user-defined intervals. There are no alarms associated with the measurement, except for a message and an auditory beep for leads off situations. To simplify the patient connections, a series of preconfigured lead sets for different EEG measurements are available. The lead wires are connected together by a plastic piece, which has labels indicating where to attach which lead. The lead wire goes through the plug so that the connectors of the wire are visible from the other side to be plugged into the headbox. The lead set has an identification pin by which the monitor can automatically select the correct montage. There are 8 different lead sets, of which 3 are preconfigured and 5 are empty ones, for the user's own montages. The length of the leads is 0.60 m. The headphones for AEP monitoring are connected to a standard 3.5 mm stereo female plug in the headbox. The headphones supplied by Datex-Ohmeda generate the sound wave in a speaker, from where the pulse is transmitted to the ear through plastic tubes. Standard safety pin EEG leads and commercial headphones can also be used with the device.

The accessories are the same for the E- EEG module and the predicate device, the M- EEG (K000892).

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INTENDED USE as required by 807.92(a)(5)

Intended Use:
Intended use:
The Datex-Ohmeda S/5™ EEG module , E-EEG and the Datex-Ohmeda S/5™ EEG headbox, N-EEG are intended to be used with Datex-Ohmeda modular multiparameter monitors for monitoring neurophysiological status of hospitalized patients.

Indications for use:
The Datex-Ohmeda S/5™ EEG module , E-EEG and the Datex-Ohmeda S/5™ EEG headbox, N-EEG and accessories are indicated for monitoring of electroencephalograph (EEG), frontal electromyograph (FEMG) and auditory evoked potentials (AEP) of all hospital patients.
The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5™ EEG Module, E-EEG and Datex-Ohmeda S/5™ EEG Headbox, N-EEG and accessories is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M- EEG Module (K000892).

The E- EEG module has the following similarities compared to the predicate M- EEG (K000892):

- identical intended use and indications for use
- identical fundamental scientific technology
- identical electronic measurement board
- same module software
- same EEG-specific monitor software
- use the same operating principle
- identical accessories and headbox N-EEG
- have the same user interface at the monitor and alarms (can be used with the same monitor software)
- the Customer and parameter specifications are the same
- have the same safety and effectiveness
- are manufactured using the same processes

The main differences between the new E-EEG and the predicate M-EEG (K000892) is primarily due to fact that the new E-EEG module has the following changes:

- new color, shape, and size and thus differing mechanics
- The front panel and labeling have changed
- New layout of electronic input board between module connector and measurement board

Based on the analysis and other documentation included in this 510(k) notification and attachments it is evident that the main features and indications for use of the Datex-Ohmeda S/5™ EEG Module, E-EEG are substantially equivalent to the predicate Datex-Ohmeda M- EEG Module (K000892).

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SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5™ EEG Module, E-EEG is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M- EEG Module (K000892) have been assessed against the standards below. The device has been thoroughly tested through validation and verification of specifications.

- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices
- FDA/DCRND Reviewer Guidance for Premarket Notification Submissions, November 1993
- IEC 60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995 (Part 1: General requirements for safety)
- EN 60601-1:1990+ A1:1993 + A13:1996 + A2:1995 (identical to IEC60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995)
- CAN/CSA C22.2 No. 601.1-M90 + S1:1994 (Canadian deviations to IEC 60601-1:1988 + Amdt. 1:1991) + S2:1998 (=IEC Amdt 2:1995)
- IEC 60601-1-2:2001 (Electromagnetic compatibility – Requirements and tests)
- AAMI ES1-1993 (Safe current limits for electromedical apparatus)
- Electroencephalograph Devices Guidance for 510(k) Content, Draft Document Version 1.0 November 3, 1997
- FDA/ODE Guidance for Content of Premarket Submission for Software Contained in Medical Devices. (May 11, 2005)
- IEC 60601-2-26 Medical electrical equipment. Part 2: Particular requirements for the safety of electroencephalographs, 2002.
- ISO 14971 Ed. 1: Medical devices - Application of risk management to medical devices
- FDA Performance standard, 21 CFR Part 898.12

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5™ EEG Module, E-EEG is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M- EEG Module (K000892).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 5 - 2005

Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
GE Healthcare
86 Pilgrim Road
Needham, Massachusetts 02492

Re: K051883
Trade/Device Name: Datex-Ohmeda S/5™ EEG Module, E-EEG and
Datex-Ohmeda S/5™ EEG Headbox, N-EEG and Accessories
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWJ, GWQ, IKN
Dated: July 10, 2005
Received: July 12, 2005

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051883

Device Name: Datex-Ohmeda S/5™ EEG Module, E-EEG and Datex-Ohmeda S/5™ EEG Headbox, N-EEG and Accessories.

Indications for Use:

The Datex-Ohmeda S/5™ EEG module , E-EEG and the Datex-Ohmeda S/5™ EEG headbox, N-EEG and accessories are indicated for monitoring of electroencephalograph (EEG), frontal electromyograph (FEMG) and auditory evoked potentials (AEP) of all hospital patients.

The device is indicated for use by qualified medical personnel only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051883